K002172 (P.1 OF 4)

AUG 2 8 2001

Innovative Research
for Orthopaedic Solutions

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SECTION 8: 510(k) SUMMARY

Revised 16 August 2001

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

A. SUBMITTER

Xiros plc (incorporating Neoligaments Ltd)
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B. COMPANY CONTACT

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Quality Assurance Manager

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C. DEVICE NAME

Trade Name: Poly-Tapes
Common Name: Non-absorbable Polyester Surgical Tape
Classification: Non-absorbable poly(ethylene terepthalate) surgical suture.

D. PREDICATE LEGALLY MARKETED DEVICES

1. Deknatel "Cottony II" Flat Braided Polyester Tape (Deknatel, Fall River, MA).
2. Acufex EndoButton Tape Polyester Surgical Suture (Smith and Nephew Endoscopy, Mansfield MA).
3. Sherwood, Davis and Geck Polyester Tape (American Cyanamid, Danbury, CT).
4. Ethicon Mersilene Polyester Tape (Johnson and Johnson).
5. USP Nonabsorbable Surgical Suture.

E. DEVICE DESCRIPTION

Poly-Tapes are woven implantable flat tapes, either single layer or tubular (double construction).

Poly-Tapes are available for this application in extra-strong, dense woven construction, and in widths from $^{1}/_{8}$" – $^{1}/_{5}$" (3 to 5 mm) and length in the range of 12" – 32" (30 cm – 80 cm). They may be provided either with or without an attached standard stainless steel surgical needle at one end.

F. INTENDED USE

Poly-Tapes are single use devices intended to be used for soft tissue approximation, including Achilles tendon repair in patients with acute rupture of Achilles tendon.

G. PERFORMANCE

Poly-Tapes have been thoroughly tested against the predicate devices for their indicated use of soft tissue approximation (see Table 8-1 *Equivalence Comparison of Poly-Tapes with Predicate Devices* and Table 3-1 *Compliance of Poly-Tapes with USP XXIII Requirements for Class I non-absorbable surgical sutures.*) They are substantially similar, but superior in strength and stiffness.

The Clinical performance of Poly-Tapes used for Achilles tendon reconstruction is reported in Section 4 and Appendix VIII of this notification.

H. TECHNOLOGICAL CHARACTERISTICS

Poly-Tapes are flat suture tapes woven with various structures from poly(ethylene terephthalate). Table 8-1 *Equivalence Comparison of Poly-Tapes with Predicate Devices* shows key technological characteristics including Design (construction), Materials, Performance, Sizes and Standards. The woven structure of Poly-Tapes gives enhanced strength and stiffness compared with USP sutures and the predicate devices (which are braided).

K002172 (p. 3 of 4)

Table 8-1: Equivalence comparison of Poly-Tapes with predicate devices # 1-4 (amended)

Aspect	Poly-Tapes	Deknatel Tape	Endo-Tape	S, D & G Tape	Mersilene Tape
Manufacturer	Xiros plc	Deknatel	Acufex/Smith & Nephew	Sherwood, Davis & Geck (Cyanamid)	Ethicon (J&J)
Basis for sale within USA	Pending				
Indications for use	Soft tissue approximation including acute Achilles tendon repair.	Soft tissue approximation	General soft tissue approximation	Soft tissue approximation	Soft tissue approximation
Class	II	II	II	II	II
Design	Woven: flat or flat tubular, dense structure.	Braided	Braided	Braided	Braided
Lengths	16" – 32" (40 cm – 80 cm)	12" – 30" (30 cm – 75 cm)	12" – 30" (30 cm – 75 cm)	12" – 30" (30 cm – 75 cm)	12" – 30" (30 cm – 75 cm)
Width (flat)	$^1/_8$" – $^1/_5$" (3 mm – 5 mm)	$^1/_8$" or $^1/_5$" (3 mm or 5 mm)	$^1/_5$" (5 mm)	$^1/_8$" or $^1/_5$" (3 mm or 5 mm))	$^1/_5$" (5 mm)
Materials	Polyester poly (ethylene terephthalate)	Polyester poly (ethylene terephthalate)	Polyester poly (ethylene terephthalate)	Polyester poly (ethylene terephthalate)	Polyester poly (ethylene terephthalate)
Performance:	see Tables 4-1 and 4-2 and Section 4.				
Sterility	Sterile: gamma-radiation SAL = 10^{-6}	Sterile:	Sterile: ethylene oxide	Sterile: gamma	Sterile: gamma
Standards (for deviations see Table 3-1 Requirements 4, 6 & 13).	USP XXIII Non-absorbable suture	USP XXIII Non-absorbable suture	USP XXIII Non-absorbable suture	USP XXIII Non-absorbable suture	USP XXIII Non-absorbable suture

* we have not been able to verify this 510(k) number.

I. SUBSTANTIAL EQUIVALENCE

Poly-Tapes and the predicate devices # 1 - 4 above have superficially similar design, same dimensions, and are made from the same material. They comply to an equal degree with 21 CFR 878.5000.

A point-by-point comparison of the Poly-Tapes with predicate devices # 1 – 4 is given in Table 8-1 of this 510(k) Summary section. Further information on mechanical performance testing supporting the claim of equivalence is summarized in paragraph I, below.

The choice and control of materials and processes, and quality management systems complying with ISO 9001/EN 46001 and 21 CFR 820, all provide the necessary assurance of device safety, including sterility. The polyester used has a long history of safe implantation in a number of devices, and is tested in accordance with ISO 10993-1.

J. NON-CLINICAL PERFORMANCE TEST DATA

Xiros plc has conducted the following laboratory tests of Poly-Tapes and a predicate device:

1. USP knot pull test for Sutures;
2. Tensile test of unknotted tapes;

In tests 1 and 2 the chosen predicate device used for comparison was the 5 mm Deknatel White Cottony II tape. The 3 mm Poly-Tapes tested were stronger and more stiff than the Dekatel tape, in both tests. They are stronger than the strongest USP non-absorbable suture (see Table on page 3 of *Proposed Initial USA Package Insert Labelling For Poly-Tapes,* Appendix VIa).

K. CLINICAL PERFORMANCE DATA

The indication for use in Achilles tendon repair is supported by the Performance data (Section 4) and clinical data in Appendix VIII. The cited reports show that the Poly-Tape is safe and effective for repairing Achilles tendon ruptures. No re-ruptures have occurred. Other complications were few, and mostly typical of those associated with surgical intervention in this condition. Table 1 in the Evaluation (in Section 4, Performance) summarizes and compares data from clinical reports concerning Poly-Tapes for the repair of ruptured Achilles tendons and from clinical reports involving operative and no-operative treatments for this condition.

Signed _____ J.R.J. Rowland Date: 16 August 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2001

Mr. Jim Rowland
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Re: K002172
Trade/Device Name: Poly-Tapes
Regulation Number: 878.5000
Regulatory Class: II
Product Code: GAT
Dated: May 25, 2001
Received: May 31, 2001

Dear Mr. Rowland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002172

INDICATIONS FOR USE

Revised 16 August 2001

Poly-Tapes are single use devices intended to be used for soft tissue approximation, including Achilles tendon repair in patients with acute rupture of the Achilles tendon.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002172